From the Western Vascular Society

Clinical consequence of bare metal stent and stent graft failure in femoropopliteal occlusive disease

Shant M. Vartanian, MD,[a] Paul C. Johnston, MD,[b] Joy P. Walker, MD,[a] Sara J. Runge, MD,[a] Charles M. Eichler, MD,[a] Linda M. Reilly, MD,[a] Jade S. Hiramoto, MD,[a] and Michael S. Conte, MD,[a]
San Francisco, Calif; and Denver, Colo

Objective: **The optimal role for bare metal stents (BMS) or stent grafts (SG) in femoropopliteal occlusive disease (FPOD) is as of yet undefined. Understanding the clinical consequences of failure can help guide initial treatment decisions. The goal of this study was to define the nature, frequency, and risk factors for adverse clinical events related to BMS and SG failure in FPOD.**

Methods: **This is a single-institution retrospective review of primary endovascular interventions for FPOD using either a BMS or SG, from September 2007 through October 2011. Patients were excluded if they had any previous lower extremity interventions. Patient demographics, indications for intervention, anatomic characteristics, procedural details, clinical outcomes, and reintervention details were reviewed. Clinical outcomes included the composite end point of any reintervention, amputation, or stenosis, acute limb ischemia (ALI), and the composite end point of major adverse limb events, which included a need for bypass, thrombolysis, or major amputation.**

Results: **Seventy-one limbs were treated with BMS and 63 with SG. Although patient demographics were largely similar between cohorts, key differences included indication for intervention (percent claudication BMS vs SG, 34/71 (48%) vs 42/63 (67%); $P < .05$) and the TransAtlantic Inter-Society Consensus II classification of lesions in the claudicant subgroup (TransAtlantic Inter-Society Consensus D BMS vs SG, 4/34 (12%) vs 17/42 (40%); $P < .01$). Freedom from reintervention at 1 year was better in the SG group (75% vs 64%; hazard ratio, 0.46; 95% confidence interval, 0.25-0.78; $P < .01$). Freedom from major adverse limb events was not different between groups; however, SG thrombosis resulted in a more frequent need for thrombolysis. On multivariate analysis, treating with a BMS vs SG was a significant predictor for freedom from thrombolysis (hazard ratio, 0.53; confidence interval, 0.37-0.76; $P < .01$). ALI during follow-up was seen only in the SG group (nine vs zero events, log- rank; $P < .02$).**

Conclusions: **Failure modes of BMS and SG used to treat FPOD differ, and the clinical consequences may not be benign. Claudicants may not revert back to claudication with treatment failure. Although the overall reintervention rate at 1 year is lower for SG compared to BMS, we observed a higher rate of ALI and need for thrombolysis with SG failure. In light of these differential risks of treatment failure, we believe that the use of SG as initial therapy for FPOD should be carefully deliberated and mandates close postoperative surveillance. (J Vasc Surg 2013;58:1525-32.)**

Peripheral arterial disease is abundantly prevalent, affecting up to 20% of patients over the age of 70.[1] The clinical presentation is heterogeneous, ranging from asymptomatic patients with abnormal ankle brachial indexes (ABIs) to those with critical limb ischemia (CLI). In treating patients with femoropopliteal occlusive disease (FPOD), the decision to perform a revascularization procedure is dependent on the presenting symptoms, degree of ischemia, patient-specific factors that influence life expectancy or anesthetic risk, and disease-specific factors such as lesion characteristics, arterial anatomy, and conduit availability.

Anatomically, the femoropopliteal segment is the most commonly treated infrainguinal artery. Nationally, the frequency of percutaneous revascularization techniques has increased threefold over the last decade.[2] In comparison to bypass surgery, the popularity of percutaneous methods is directly related to less patient discomfort, quicker recovery, high technical success rates, and low periprocedural morbidity.[3] Despite these advantages, there is a frequent need for reintervention and an incomplete understanding of the risk factors for and the clinical consequences of midterm or late treatment failure.

Both self-expanding nitinol stents (bare metal stents [BMS]) and stent grafts (SG) have been shown to be viable percutaneous treatment options for FPOD. Numerous single-arm series, registry data, or trials comparing each type of stent to bypass grafts individually have been reported.[4-9] To date, comparative effectiveness studies directly comparing the two have not yet been published, however, several prospective trials are nearing completion.[10] To garner the maximum benefit and cost-effectiveness of percutaneous interventions, practitioners must include a thoughtful approach to patient selection, including consideration of the

From the Division of Vascular and Endovascular Surgery, University of California, San Francisco, San Francisco[a]; and the Colorado Permanente Medical Group, Denver.[b]

Author conflict of interest: none.

Presented at the Twenty-seventh Annual Meeting of the Western Vascular Society, Park City, Utah, September 24, 2012.

Reprint requests: Shant M. Vartanian, MD, Division of Vascular and Endovascular Surgery, University of California, San Francisco, 400 Parnassus Ave A-581, Box 0222, San Francisco, CA 94143-0222 (e-mail: shant.vartanian@ucsfmedctr.org).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214/$36.00

http://dx.doi.org/10.1016/j.jvs.2013.05.094

risks for and the clinical consequences of subsequent treatment failure. The purpose of this study was to compare the nature and severity of late adverse events and the risk factors for developing those events in patients treated with either self-expanding nitinol stents or with SG in FPOD.

METHODS

This is a retrospective review of two cohorts of consecutive patients with FPOD, treated with either self-expanding nitinol stents or self-expanding SG at a single tertiary care institution from October 2007 through December 2011. Patients with previous infrainguinal interventions, either endovascular or open, were excluded from the analysis. Patients with previous inflow procedures, including aortofemoral bypasses, iliac stents, or femoral endarterectomies, and those with previous below-the-ankle amputations were included in the analysis. Patients without at least one follow-up visit postdischarge were excluded.

With the approval of the University of California, San Francisco Institutional Review Board, electronic medical records were used to compile patient demographics, comorbid conditions, medication use, indication for intervention, noninvasive vascular laboratory data, and degree of ischemia classified by the Rutherford classification system.[11] The decision to implant a BMS or an SG was at the discretion of the operating vascular surgeon. In most cases, the superficial femoral artery (SFA) was accessed percutaneously via a contralateral retrograde approach. In 22 limbs, a flush SFA occlusion with concomitant common femoral disease was treated with a hybrid femoral endarterectomy and SFA endoluminal treatment. The preintervention angiogram was used to classify atherosclerotic lesions according to the TransAtlantic Inter-Society Consensus (TASC) II classification system.[12] Chronic total occlusions (CTOs) were noted if they were present of any length. Highly calcified lesions were defined as those that are visible on fluoroscopy without the presence of contrast. Implant logs were used to capture the model, diameter, length, and number of stents implanted. Only heparin-bonded Viabahn (W. L. Gore, Flagstaff, Ariz) SG were used in the SG cohort. The BMS cohort was made up of a combination of Zilver (Cook Medical, Bloomington, Ind), Everflex (eV3 Endovascular, Plymouth, Minn), Protégé Everflex (eV3 Endovascular), Conformexx (Bard Medical, Covington, Ga), and SMART stents (Cordis, Bridgewater, NJ). The completion angiogram was used to capture the location of the stent within the SFA or popliteal artery, and a runoff score using the four-level Society for Vascular Surgery (SVS) system was calculated.[11]

Intraprocedural and postprocedural complications were reviewed. Time to discharge and discharge medications were recorded. Follow-up clinic visits were reviewed for changes in symptoms, the pulse examination, or the ABI. A surveillance ultrasound was recommended at 1 month, then every 3 months for the first year, then yearly. However, compliance with follow-up and participation in the surveillance ultrasound program was variable. The clinical presentation and indication prompting reintervention was noted, as were the degrees of ischemia by the Rutherford classification system.

The clinical end points under study were the composite end point of any ipsilateral reintervention, loss of patency without reintervention, stenosis, or major amputation (the composite outcome of reintervention, amputation, or stenosis [RAS]).[13] This included any catheter-directed or open reintervention other than below-ankle amputations. Patency was defined as absence of occlusion or a flow-limiting stenosis, defined as a peak systolic velocity >300 cm/s by duplex ultrasound or an 80% stenosis by angiography. Thrombolysis was defined as any catheter-directed thrombolysis or open thrombectomy of the treated limb as a result of stent thrombosis. Major amputations were defined as any amputation above the ankle level. A composite end point of major adverse limb events (MALE) was defined as any major amputation, bypass procedure, or need for thrombolysis. Acute limb ischemia (ALI) was defined as any sudden loss of perfusion threatening viability of the limb (Rutherford ALI classification).[11] Mortality was assessed using the Social Security Death Index.

Statistical analysis was performed using STATA 12.1 (StataCorp LP, College Station, Tex). Interval variables were analyzed using a one-way analysis of variance. Nominal variables were analyzed with a Pearson χ^2 test unless the number of observations mandated using a Fisher exact test. Nonparametric analysis of ordinal variables was performed using Wilcoxon rank-sum test. Logistic regression was used for dichotomous outcome data to test predictors for events. Survival analysis was performed for all time-to-event data. Cox proportional hazards regression was used to test predictors for clinical events. Predictors on univariate analysis that were found to be significant ($P < .10$) were included in a stepwise Cox regression model with reverse selection for significant predictors. Univariate variables individually examined included type of stent, sex, age >75, diabetes, chronic renal insufficiency, end-stage renal disease (ESRD), smoking status, statin use, claudication vs CLI, TASC classification, runoff score, presence of CTO, heavily calcified lesions, device diameter, number of stents per limb, dual antiplatelet therapy, and surveillance ultrasonography. Observations of clinical end points were assumed to be independent despite having 17 patients with bilateral interventions. All end points were re-evaluated with exclusion of nonindependent observations, and no significant differences were noted in the outcomes.

RESULTS

Patient demographics and comorbidities. One hundred thirty-four limbs in 100 patients met the inclusion and exclusion criteria—71 were treated with BMS and 63 with SG. Patient demographics were similar between groups; however, differences between the average age (BMS, 72.0 ± 12.1 vs SG, 68.5 ± 10.7; $P = .08$) and the presence of ESRD (BMS 12 vs SG 4; $P = .06$) approached significance. The remainder of the patient demographics, medical comorbidities, medication use, and smoking status were similar between groups (Table I).

Table I. Patient demographics, comorbid conditions and indications in patients undergoing percutaneous lower extremity revascularization

	BMS	*%*	*SG*	*%*	P
Number of limbs treated	71	53	63	47	
Mean age (SD)	72.0	12.1	68.5	10.7	.08
Female sex	24	34	16	25	.29
Comorbid conditions					
CAD	29	41	24	38	.75
Previous MI	12	17	10	16	.87
CHF	5	7	2	3	.45
CVA	1	1	4	6	.19
HTN	54	76	51	81	.49
DM	29	41	26	41	.96
CRI	13	18	9	14	.53
ESRD	12	17	4	6	.06
Hyperlipidemia	44	62	40	63	.86
COPD	5	7	5	8	.57
Home O_2	1	1	1	2	
Immunosuppression	3	4	0	0	.25
Smoking status					.36
Never	11	15	6	10	
Former	44	62	37	59	
Current	16	23	20	32	
Indication for intervention					
Rutherford class					**<.05**
Class 2	2	3	0	0	
Class 3	32	45	42	67	
Class 4	9	13	7	11	
Class 5	9	13	8	13	
Class 6	19	27	6	10	
Total claudicants	34	48	42	67	
Total CLI	37	52	21	33	

BMS, Bare metal stent; *CAD,* coronary artery disease; *CLI,* chronic limb ischemia; *CHF,* congestive heart failure; *COPD,* chronic obstructive pulmonary disease; *CRI,* chronic renal insufficiency (GFR <60); *CVA,* cerebrovascular accident; *DM,* diabetes mellitus; *ESRD,* end-stage renal disease; *GFR,* glomerular filtration rate; *HTN,* hypertension; *MI,* myocardial infarction; *SD,* standard deviation; *SG,* stent graft.
P values of <.05 are listed in bold.

Indications and anatomy. The indications for intervention were different between the two cohorts (Table I). Thirty-seven of 71 (52%) BMS patients presented with CLI (Rutherford class ≥4), whereas 24/63 (38%) of patients treated with SG had a manifestation of CLI ($P < .05$). By TASC II classification, the anatomy of the lesions was similar between groups (TASC C or D 27/70 BMS vs 35/63 SG; $P = .11$). However, on subgroup analysis of patients with claudication, a significantly greater number of TASC D lesions were treated with SG (4/34 BMS vs 17/42 SG; $P < .01$).

There were additional differences between the cohorts. The distribution of runoff scores was significantly worse in the BMS group ($P < .05$) (Table II). In contrast, CTOs were more common in the SG group (21/71 BMS vs 37/63 SG; $P < .01$). There was no difference in the number of hybrid procedures between groups (12/70 BMS vs 10/63 SG; P = NS). In eight limbs, the distal extent of the BMS extended to the knee joint, whereas no SG extended to that level ($P < .01$). Otherwise, the minimum device size (≤5 mm), the number of devices implanted per limb, and the degree of heavy calcification (31/71 vs 26/63; P = NS) were not different between the device groups.

Procedural complications. Intraprocedural complications were infrequent. There was one embolization event in the BMS group and three access-site complications in the SG group (P = NS). Postprocedural complications included four patients with troponin leaks and four with contrast-induced nephropathy in the BMS cohort, while in the SG cohort, one patient developed renal failure requiring hemodialysis and another developed a new cardiac arrhythmia.

Antithrombotic regimen and surveillance. The majority of patients were discharged on acetylsalicylic acid and Plavix (44/71 of BMS vs 50/63 of SG; $P < .05$) (Table III). In our early experience, patients treated with BMS were discharged on Plavix alone. In sum, 17/71 patients with BMS were on Plavix alone in comparison to 4/63 SG patients ($P < .05$). The median follow-up was 738 days (range, 27-1720) for the BMS cohort and 743 days (range, 10-2229) for the SG cohort. Surveillance ultrasounds were available in 91/134 limbs. All patients were followed with clinical examination, recording a change in symptoms or a change in the ABIs.

RAS. Significantly more patients treated with BMS required RAS compared with those treated with SG. Freedom from RAS at 1 year was 75% in the SG group and 64% in the BMS group (hazard ratio [HR], 0.46; 95% confidence interval [CI], 0.25-0.78; $P < .01$) (Fig 1). Reinterventions were prompted by a change in symptoms or a change in ABI in most, except in 15 patients where the reintervention was prompted by findings on surveillance ultrasound. Multivariable predictors of RAS (Table IV) included the presence of a CTO (HR, 1.6; 95% CI, 1.1-2.32) or ESRD (HR, 2.51; 95% CI, 1.46-4.31). Factors protective against RAS included a minimum stent diameter of ≥6 mm (HR, 0.66; 95% CI, 0.44-0.99). A BMS was protective over an SG in the multivariable analysis (HR, 0.68; 95% CI, 0.47-1.01; $P = .06$), however, it did not reach the threshold for significance. On subgroup analysis of claudicants, the only predictor for reintervention on multivariable analysis was a device diameter of ≥6 mm (HR, 0.32; 95% CI, 0.16-0.62).

MALE. There were 13 patients in the BMS cohort who were subsequently treated with an SG during follow-up. MALE and occurrence of ALI were assigned by the last treatment received. Events were also analyzed according to the first treatment received, with no major changes in our conclusions. Including the cross-over limbs by their final cohort assignment, there were 14 MALE events in the BMS group and 17 in the SG group. Overall, freedom from MALE was no different between groups (HR, 0.73; 95% CI, 0.36-1.50) (Fig 2). However, the distribution of MALE event subgroup types was significantly different (Table V). There were 2/58 patients who required thrombolysis in the BMS group in comparison to 11/76 patients in the SG group ($P < .05$). There were no bleeding complications related to thrombolysis. On multivariable analysis, the only significant predictors of need for thrombolysis were BMS vs SG

Table II. Patient anatomy and procedural characteristics of patients treated with either BMS or SG

	BMS	*%*	*SG*	*%*	P
Overall TASC II classification					
A	9	13	16	25	.11
B	34	49	12	19	
C	17	24	8	13	
D	10	14	27	43	
Claudicant subgroup TASC II classification					
A	5	15	12	29	**<.01**
B	20	61	8	19	
C	4	12	5	12	
D	4	12	17	40	
Runoff score					
0	8	11	16	25	**<.05**
1	28	40	24	38	
2	22	31	19	30	
3	12	17	4	6	
CTO	21	30	37	59	**<.01**
Heavy calcification	31	44	26	41	.79
Extent of SFA coverage					**<.05**
Proximal SFA	25		33		
Mid-SFA	49		46		
Distal SFA	52		56		
Popliteal	8		0		
Minimum device size					
≤5 mm	13	18	12	19	
≥6 mm	58	82	51	81	
Number of devices per limb (index case only)					.06
1	36	51	21	33	
2	22	31	18	29	
≥3	13	18	24	38	

BMS, Bare metal stent; *CTO,* chronic total occlusion; *SFA,* superficial femoral artery; *SG,* stent graft; *TASC,* TransAtlantic Inter-Society Consensus. *P* values of <.05 are listed in bold.

Table III. Antithrombotic regimens postprocedure and median follow-up for both cohorts

	BMS	*%*	*SG*	*%*
Postprocedure medications				
ASA + Plavix	44	62	50	79
ASA + Coumadin	4	6	3	5
Plavix + Coumadin	2	3	1	2
ASA	3	4	3	5
Plavix	17	24	4	6
Coumadin	1	1	1	2
Follow-up, days				
Median	738		743	
SD	541		522	

ASA, Acetylsalicylic acid; *BMS,* bare metal stent; *SD,* standard deviation; *SG,* stent graft.

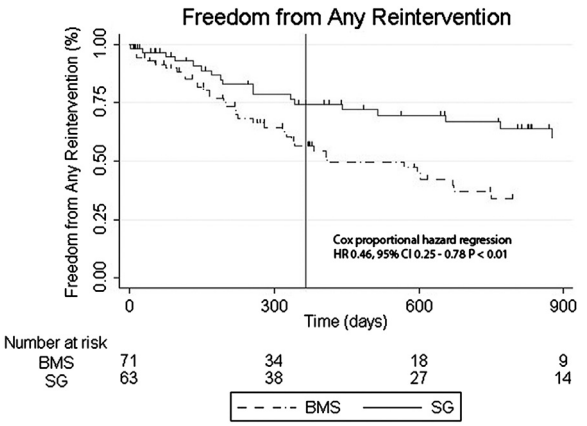

Fig 1. Freedom from reintervention, amputation, or stenosis (RAS) survival estimates, stratified by type of stent used. The vertical reference line is set at 1 year. A Cox proportional hazard regression (hazard ratio [*HR*], 0.46; 95% confidence interval [*CI*], 0.25-0.78) demonstrates the difference between the two cohorts. *BMS,* Bare metal stent; *SG,* stent graft.

(HR, 0.53; 95% CI, 0.37-0.76) and presence of a CTO (HR, 1.48; 95% CI, 1.03-2.11). There were four major amputations in the BMS group in comparison to no amputations in the SG group. The time to major amputation was 35, 77, 98, and 115 days. Over the course of the follow-up period, there were 33 deaths. There were no deaths within 30 days of the index procedure.

ALI. A clinical presentation of ALI during follow-up was observed only within the SG-treated patients (nine vs zero, log-rank $P < .02$) (Fig 3). Five patients presented with Rutherford class IIa ischemia and one with a Rutherford class IIb ischemia. In five of these nine patients, the indication for the initial intervention was claudication. The preprocedure TASC classification included three patients

Table IV. Multivariable analysis of predictors for major clinical events

	HR	*95% CI*	P
Any reintervention			
BMS vs SG	0.68	0.47-1.01	.058
CTO	1.6	1.10-2.32	<.05
ESRD	2.51	1.46-4.31	<.01
Diameter ≥6 mm	0.66	0.44-0.99	<.05
MALE			
ESRD	3.43	1.99-5.94	<.01
Thrombolysis			
BMS vs SG	0.53	0.37-0.76	<.01
CTO	1.48	1.03-2.11	<.05
ALI			
BMS vs SG	0.52	0.36-0.75	<.01
CTO	1.44	1.00-2.06	<.05

ALI, Acute limb ischemia; *BMS,* bare metal stent; *CI,* confidence interval; *CTO,* chronic total occlusion; *ESRD,* end-stage renal disease; *HR,* hazard ratio; *MALE,* major adverse limb event; *SG,* stent graft.
A stepwise Cox regression with backward selection for variables identified on univariate analysis was used to construct the models. Only significant findings are included.

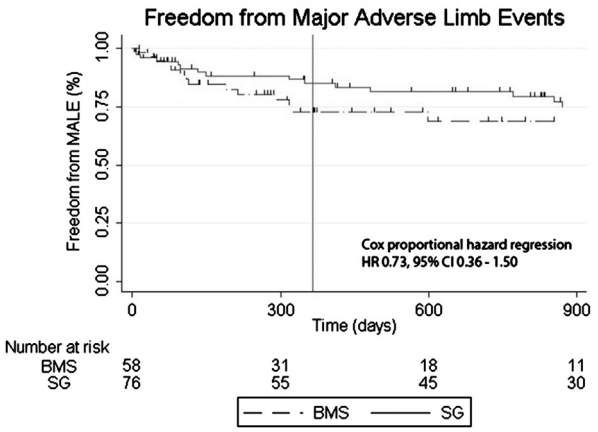

Fig 2. Survival estimates for freedom from major adverse limb events (MALE). The difference between estimates is not significant. *BMS,* Bare metal stent; *CI,* confidence interval; *HR,* hazard ratio; *SG,* stent graft.

with TASC A lesions. On multivariable analysis, predictors for ALI included the type of stent used (BMS vs SG; HR, 0.52; 95% CI, 0.36-0.75) and presence of a CTO (HR, 1.44; 95% CI, 1.0-2.1). Four patients required a bypass operation, two required thrombolysis followed by a bypass, and three were salvaged with thrombolysis followed by repeat stenting. Four of the nine patients with ALI had lost runoff because of thrombus in the infrageniculate vessels. Two of the four were salvaged with thrombolysis (Table VI).

Clinical deterioration. On subgroup analysis of patients whose initial indication for intervention was claudication, 5/34 (9%) limbs treated with BMS progressed to CLI during follow-up. In comparison, 13/42 (17%) limbs in the SG cohort progressed from claudication to either CLI or ALI when the SG failed ($P = .16$).

Table V. A summary of major late clinical events in both cohorts

	BMS	*%*	*SG*	*%*	P
Any reintervention	41	58	22	35	**<.01**
Number of crossovers	13		0		
MALE	14	24	17	22	.71
Bypass	9	16	14	18	
Thrombolysis	2	3	11	14	
Major amputation	4	7	0	0	
ALI	0		9	12	**<.05**
Stage I			3	4	
Stage IIa			5	7	
Stage IIb			1	1	
Net change in Rutherford class					
Claudicants progressing to CLI	5	13	4	7	.27
Claudicants progressing to CLI + ALI	5	13	13	17	.15

ALI, Acute limb ischemia; *BMS,* bare metal stent; *CLI,* chronic limb ischemia; *MALE,* major adverse limb event; *SG,* stent graft.
P values of <.05 are listed in bold.

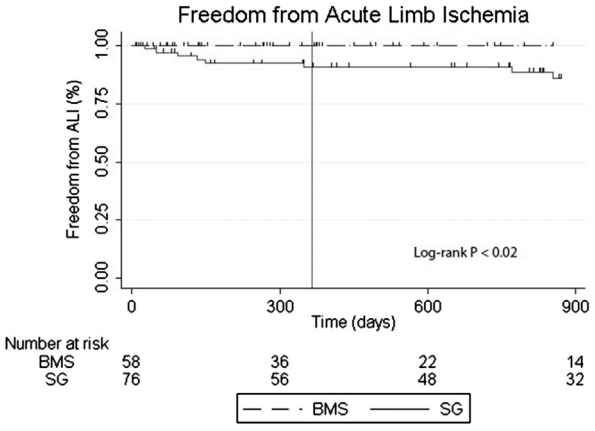

Fig 3. Survival estimates for freedom from acute limb ischemia (ALI). There were no ALI events in the bare metal stent (*BMS*) group. *SG,* Stent graft.

DISCUSSION

The purpose of this study was to investigate differences in the frequency and magnitude of late adverse clinical events in patients with FPOD treated with self-expanding nitinol stents or with SG and to identify risk factors for those events. A number of important differences in outcomes between the groups were observed, however, these findings must be interpreted with an understanding of important limitations of our study design.

Despite our best effort to study similar cohorts of patients, there were a number of key differences between groups that could help account for our observations. We limited our study to patients who underwent percutaneous

Table VI. A summary of ALI events, including indication for intervention, lesion anatomy by TASC II classification, and the clinical outcome of the limb

ALI event number	*Preprocedure Rutherford classification*	*TASC II*	*Loss of runoff*	*Outcome*
1	3	D	Yes	Bypass
2	5	D	No	Thrombolysis with repeat stenting
3	3	C	Yes	Thrombolysis with bypass and fasciotomy
4	4	D	Yes	Bypass
5	6	A	No	Thrombolysis with repeat stenting
6	4	A	No	Bypass
7	3	A	No	Bypass
8	3	D	No	Thrombolysis with repeat stenting
9	3	D	Yes	Thrombolysis with bypass

ALI, Acute limb ischemia; *TASC,* TransAtlantic Inter-Society Consensus.

interventions on their initial presentation for lower extremity occlusive disease. This excluded patients with previous treatment failures and minimized the selection bias by studying patients who had been deemed a good fit for endovascular interventions. Overall, the demographics and comorbid conditions were similar, but key differences in indication and anatomy were present. Significantly more claudicants were treated with SG than BMS. Although overall the anatomic pattern of disease between the two groups was similar, subgroup analysis of claudicants showed more TASC D lesions were treated with SG than BMS (40% vs 12%). Other differences such as runoff status, percentage of limbs with CTOs, and the location of the stents also differed. These differences limit the ability to make direct comparisons between groups, but also likely represent "real-world" application of the competing technologies, and hence, the results are noteworthy.

Overall, the 1-year freedom from reintervention rate for SG was 75%. Our 1-year results were similar to most other reports regarding SG in FPOD. Of the larger randomized trials using SG in the SFA, Kedora et al showed a 1-year primary patency rate of 72% in a prospective trial comparing SG against a prosthetic surgical bypass.[9] Saxon et al had observed a primary patency rate of 65%.[8] The VIBRANT trial has reported interim results, but the primary end point of 3-year follow-up has not yet been published. In their presentation, 1-year primary patency was 53%. It should be noted that unlike in those trials, all the limbs in our study were treated with a heparin-bonded device. Whether the heparin-bonded surface confers an additional clinical advantage is unknown.

The reintervention rate was significantly higher for BMS at 1 year. Well-known risks for reintervention following stent placement for FPOD include vessel diameter, length of lesion treated, and runoff status.[14-16] The results presented here echo these findings, and on multivariable analysis, stent diameter of <6 mm and treating CTOs were predictors for reintervention. In addition, ESRD and treating with BMS vs SG were also predictors for needing reintervention. Whether this is related to patterns of diffuse in-stent stenosis seen in BMS as opposed to edge stenosis seen in SG is speculated but unknown.

Our most salient finding relates to the severity of ischemia following failure of these interventions. Claudicants treated with either technology did not necessarily revert back to claudication when the percutaneous treatment failed. Of the 34 claudicant limbs treated with BMS, five (9%) subsequently presented with CLI, whereas of the 42 limbs treated with SG, 13 (17%) subsequently presented with either CLI or ALI. Although these findings were not statistically significant ($P = .16$), the absolute difference of 9% vs 17% suggests that a study examining larger numbers of patients or longer follow-up periods may prove the difference to be real.

We also observed that a significant number of patients treated with SG developed ALI following SG thrombosis. We did not observe ALI in the BMS group. These events occurred evenly in patients with initial presentations of CLI or claudication, and surprisingly, they occurred in three out of nine patients who had TASC A lesions. In sum, 12% of the total SG cohort ultimately presented with ALI at a later time. The only predictor for ALI on multivariable analysis was SG use and the presence of a CTO. In the Viabahn Endoprosthesis vs Bare Nitinol Stent study (VIBRANT) trial, which is a prospective study of claudicants, 1-year data presented in abstract form notes that 9/72 (13%) claudicants treated with SG developed subsequent CLI or ALI, in comparison to 6/76 (8%) patients treated with BMS that had progression of their claudication on device failure. We await publication of these study results.

The composite end point of MALE was not different between the groups; however, the types of MALE events were different. Freedom from MALE was no different in large part because of the number of major amputations in the BMS group (n = 4), whereas there was no amputation in the SG cohort. As all the major amputations were in patients with Rutherford class VI ischemia, and the time to amputation for all events was within 4 months of the BMS placement, it can be argued that primary amputation should have been considered rather than aggressive limb salvage in these cases.

Conversely, thrombolysis was far more prevalent in SG failure. Our group has previously shown a high rate of thrombolysis for limbs treated with SG, and although the patients in this cohort are different than the patients in that study, we found similar results in this group as well.[17] It should be noted that in most cases, thrombolysis was used to re-establish patency within the SG, rather than to salvage lost runoff, although four patients did have distal embolization related to SG thrombosis with subsequent loss of runoff. The timing of the embolization is uncertain, and we cannot exclude the possibility that embolization occurred either while crossing the thrombosed SG or during the thrombolysis process.

Our group has also published similar findings in a differing group of patients. Johnson et al noted similar rates of reintervetion, MALE, and ALI in all patients with FPOD treated with SG. There are significant differences between the cohort of patients in that report and this series. In this study, only patients undergoing their index procedure for FPOD were included, whereas in Johnson et al, nearly one-third of patients had a previous BMS that were relined with an SG. This series is also more contemporary, including only patients after 2007. This limited the effect of device modifications on outcomes, including the addition of a bioactive heparinzed surface. Multivariable analysis of risk factors for reintervention and MALE were complementary, although one difference was the effect of dual antiplatelet therapy. In our series, this was not a risk factor for any of the end points under study. This may be a result of a sampling error, as only 13% of the SG cohort was on a single agent.

Another limitation of this study is the lack of detailed data about the cost of each intervention or reintervention. The cost of the sum of the interventions coupled with pretreatment levels of disability and functional outcomes are important in determining the value of each treatment. The rapid introduction of new and diverse technologies for treating infrainguinal occlusive disease, and the paucity of comparative effectiveness research comparing techniques, makes choosing a single optimal treatment strategy difficult. The picture may become even more muddled with the introduction of drug-eluting balloons and stents.

In conclusion, although the reintervention rate for FPOD treated with SG may be lower, the clinical presentation of failed percutaneous treatment is different between BMS and SG. SG failure is more likely to present with advanced ischemia, including a 10% rate of ALI. In light of the high risks associated with failure, patients should be carefully selected for percutaneous interventions, particularly claudicants with TASC D lesions. SG should not be used indiscriminately in claudicants with FPOD, as the risks associated with treatment failure may be worse than the natural history of untreated disease.

AUTHOR CONTRIBUTIONS

Conception and design: SV, PJ, MC
Analysis and interpretation: SV, CE, LR, JH, MC
Data collection: SV, PJ, JW, SR
Writing the article: SV
Critical revision of the article: SV, PJ, JW, SR, CE, LR, JH, MC
Final approval of the article: SV, PJ, JW, SR, CE, LR, JH, MC
Statistical analysis: SV
Obtained funding: Not applicable
Overall responsibility: SV

REFERENCES

1. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation 2006;113:e463-654.
2. Goodney PP, Beck AW, Nagle J, Welch HG, Zwolak RM. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. J Vasc Surg 2009;50:54-60.
3. Lin PH, Weakley SM, Kougias P. How to interpret data from the superficial femoral artery stenting trials and registries. Semin Vasc Surg 2010;23:38-47.
4. Laird JR, Katzen BT, Scheinert D, Lammer J, Carpenter J, Buchbinder M, et al. Nitinol stent implantation vs balloon angioplasty for lesions in the superficial femoral and proximal popliteal arteries of patients with claudication: three-year follow-up from the RESILIENT randomized trial. J Endovasc Ther 2012;19:1-9.
5. Schillinger M, Sabeti S, Loewe C, Dick P, Amighi J, Mlekusch W, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med 2006;354:1879-88.
6. Krankenberg H, Schluter M, Steinkamp HJ, Burgelin K, Scheinert D, Schulte KL, et al. Nitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: the femoral artery stenting trial (FAST). Circulation 2007;116:285-92.
7. Alimi YS, Hakam Z, Hartung O, Boufi M, Barthelemy P, Aissi K, et al. Efficacy of Viabahn in the treatment of severe superficial femoral artery lesions: which factors influence long-term patency? Eur J Vasc Endovasc Surg 2008;5:346-52.
8. Saxon RR, Coffman JM, Gooding JM, Ponec DJ. Long-term patency and clinical outcome of the Viabahn stent graft for femoropopliteal artery obstructions. J Vasc Interv Radiol 2007;18:1341-9; quiz 1350.
9. Kedora J, Hohmann S, Garrett W, Munschaur C, Theune B, Gable D. Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease. J Vasc Surg 2007;45:10-6; discussion: 16.
10. Geraghty PJ. Covered stenting of the superficial femoral artery using the Viabahn stent-graft. Perspect Vasc Surg Endovasc Ther 2006;18:39-43.
11. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
12. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg 2007;33(Suppl 1):S1-75.
13. Conte MS, Geraghty PJ, Bradbury AW, Hevelone ND, Lipsitz SR, Moneta GL, et al. Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia. J Vasc Surg 2009;50:1462-73.e1.
14. Ihnat DM, Mills JL Sr. Current assessment of endovascular therapy for infrainguinal arterial occlusive disease in patients with diabetes. J Vasc Surg 2010;52(3 Suppl):92S-5S.
15. Davies MG, Saad WE, Peden EK, Mohiuddin IT, Naoum JJ, Lumsden AB. Impact of runoff on superficial femoral artery endoluminal interventions for rest pain and tissue loss. J Vasc Surg 2008;48:619-25; discussion: 625-6.
16. DeRubertis BG, Pierce M, Chaer RA, Rhee SJ, Benjeloun R, Ryer EJ, et al. Lesion severity and treatment complexity are associated with outcome after percutaneous infra-inguinal intervention. J Vasc Surg 2007;46:709-16.
17. Johnston PC, Vartanian SM, Runge SJ, Hiramoto JS, Eichler CM, Owens CD, et al. Risk factors for clinical failure after stent graft treatment for femoropopliteal occlusive disease. J Vasc Surg 2012;56:998-1006.

Submitted Feb 11, 2013; accepted May 29, 2013.